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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,772	03/07/2005	Kazuki Endo	2005_0017A	2421

513 7590 05/29/2008

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EXAMINER	
JAVANMARD, SAHAR	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
05/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,772	ENDO ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 and 8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/11/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to Applicant's arguments filed on 1/11/2008. Claim(s) 6 and 8-10 are pending. Claims 6 and 9-10 are amended. Claims 6 and 8-10 are examined herein.

Response to Arguments

Applicant's amendments have rendered the 112 1st rejection of claims 6-10 as it applies to the removal of the term "prophylaxis" are moot, therefore the rejection is withdrawn.

Applicant's amendments have rendered the 102(b) rejection, as anticipated by Foguet et al. (WO 01/72288), of claims 7 and 16-20 moot, therefore the rejection is withdrawn.

Applicant's arguments with respect to the 102(b) rejection of claims 6 and 8-10 as being unpatentable over Foguet et al. (WO 01/72288) has been fully considered but found not persuasive as Applicant is now arguing based on amended claims. Since Applicant has amended the claims, said rejection is hereby withdrawn.

In view of Applicant's amendments, the 103(a) rejection, as obvious by Foguet et al. (WO 01/72288) in view of Remington ("The Science and Practice of Pharmacy,

Nineteenth Edition, vol. 1, 1985, page 806), of claim 21 moot, therefore the rejection is hereby withdrawn.

Applicant's amendments necessitated the following modified rejections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foguet et al. (WO 01/72288A2).

Foguet teaches the administration of cytidine 5'-diphosphocholine (CDP-choline) for the treatment of alcohol withdrawal syndrome. The reference teaches that chronic alcohol abuse has been reported to impair dopamine sensitivity; an effect that probably arises from changes in neuronal membrane fluidity and in the number and functionality of receptors (page 1, all).

Additionally, Foguet teaches that in the clinical study of CDP-choline wherein alcohol withdrawal syndrome was assessed, a significant improvement on anxiety tremor, disorientation, insomnia, dysarthria, tendency to suicide and neuritic pains was observed (page 6, example 4).

Further, Foguet teaches that CDP-choline can be administered orally or parentally (page 3, lines 3-9) and in the form of tablets, capsules, powder, granules, cachets, lozenges, solution, suspension, emulsion, syrup, and the like (page 3, lines 21-25; example 1 and 2).

Foguet does not specifically teach "peripheral" neuropathy.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have known that in addition to treating neuropathy derived from the central nervous system as taught by Foguet, that peripheral neuropathy would also be treated. This is taught by Foguet, as discussed above, wherein neuritic pains, in addition to other symptoms, are improved upon administration of CDP-choline. As is known to one of ordinary skill in the art, neuritic pains arise from the periphery, thus it would have been obvious that the administration of CDP-choline would also be effective in treating drug-induced peripheral neuropathy.

Conclusion

Claims 6 and 8-10 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617